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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,250	09/30/2003	Niklas Axen	1510-1066	2853
466	7590	02/01/2005	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			WOOD, ELIZABETH D	
			ART UNIT	PAPER NUMBER
			1755	

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/673,250	Applicant(s) AXEN ET AL.	
	Examiner Elizabeth D. Wood	Art Unit 1755	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 20 December 2004.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) 23 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-22 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/30/03</u> .	6) <input type="checkbox"/> Other: _____

Specification

The examiner has not checked the specification to the extent necessary to determine the presence of **all** possible minor errors (grammatical, typographical and idiomatic). Cooperation of the applicant(s) is requested in correcting any errors of which applicant(s) may become aware of in the specification, in the claims and in any future amendment(s) that applicant(s) may file.

Applicant(s) is also requested to complete the status of any copending applications referred to in the specification by their Attorney Docket Number or Application Serial Number, **if any**.

The status of the parent application(s) and/or any other application(s) cross-referenced to this application, if **any**, should be updated in a timely manner.

The abstract of the disclosure is objected to because it fails to provide proper antecedent basis for claims 17, 20, 21 and 22. The specification indicates that the cement composition "can further be used for manufacturing" implants and so forth, but does not specifically refer to the implants themselves. Further, the specification does not appear to provide antecedent basis for the recitation of a "device". Correction is required. See MPEP § 608.01(b).

Oath

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Election/Restriction

Applicant's election with traverse of Group I in the reply filed on December 20, 2004 is acknowledged. The traversal is on the ground(s) that a "drug carrier" constitutes an intended use and therefore should not be restricted. This is not found persuasive because claims 17 and 20-23 are not drawn to "intended uses" or they would not be examined since intended use claims are non-statutory. The claims recite articles and imply structure. The "drug carrier" of claim 23, however, further can include the drug itself due to the claim language of "comprising", and as long as the drug can be considered a part of the claim, restriction remains proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Interpretation

Applicant should note that the instant claims employ the language "preferably". The examiner has not considered any of the text in the claims subsequent to the word "preferably". If applicant wishes the examiner to consider claims of this scope, then the

information found after the term "preferably" should be presented in dependent claims and this language should be removed from the independent claims.

Applicant should further note that the instant claims employ the language "such as". The examiner has not considered any of the text in the claims subsequent to the words "such as". If applicant wishes the examiner to consider claims of this scope, then the information found after the term "such as" should be presented in dependent claims and this language should be removed from the independent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the terminology "more than 50 vol.% of CA and C₁₂A₇". It is unclear from this recitation whether **both** phases must be present in some amount because this phrase can be considered to read on either phase alone, so long as one phase is present in an amount larger than 50 vol.%.

The claims are further indefinite in the recitation of "suitable additives" absent a definition of "suitable".

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Applicant's claims 4, 5, 6, 9 and 11 employ the incorrect Markush terminology "selected from the group comprising". This should be amended to recite "selected from the group consisting of".

Claim 6 further employs the terminology "based on". The metes and bounds of this claim are therefor unclear.

Claim 6 further employs a trademark in the claim. This is not proper.

Claim 12 is indefinite in that the claim from which it depends lacks any antecedent basis for the recitation of "powder/particle raw material".

Claim 13 does not appear to further limit the composition. This is apparently an inherent characteristic of the ceramic material.

In claim 14, "0,8" should be changed to "0.8".

Claim 17 is indefinite in the terminology "medical device". This terminology is not defined by the specification and the metes and bounds of the claims are therefore unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for medical implants, orthopedic implants, dental implants and drug carriers, does not reasonably provide enablement for a claim to a "medical device". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

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invention commensurate in scope with these claims. The skilled artisan could not make and use the invention commensurate in scope with a "device" absent undue experimentation. This language includes myriad articles neither contemplated nor disclosed by applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 8, 9, and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,652,593 to Kawahara et al.

The instantly claimed invention involves a ceramic composition, method for the production thereof and articles containing the composition. Claim 1 is representative of the composition, which comprises calcium aluminate phases CA and/or $C_{12}A_7$ in an amount over 50 vol.% and optionally other additives and other CA phases.

Kawahara et al. disclose a dental cement composition comprising powdered calcium aluminate compounds of the phases claimed herein and methods for the production thereof. They are considered to be present in amounts greater than 50%. They can also contain sulfates phosphates, hydroxides and carbonates of calcium as found in applicants dependent claims. They disclose cellulose materials as set forth in the dependent claims. They recite a powder particle size commensurate with that set forth herein. They disclose sintering, which would remove organic material. They disclose articles consistent with the claims herein. They disclose aqueous solutions to cure the material. See particularly column 2, lines 37+, column 3, lines 40+ and the examples.

Kawahara et al. are considered to differ from the instant claims in that they don't recite the claimed requirements of less than 50 vol.% of CA_2 and less than 10 vol.% of C_3A . However, since these amounts include zero, the instant claims would have been obvious.

Since the composition of Kawahara is substantially the same as that disclosed by applicants, limitations such as expansion and temperature generation are considered inherent to the composition.

Claims 3, 4, 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawahara et al. as applied to the claims above, and further in view of SE 010441-1.

These claims simply recite well-known additives in dental cement materials such as perovskites, LiCl, fumed silica, superplasticizers, water-reducing agents, etc. SE 010441-1 is relied upon only to demonstrate that these additives are known and would have been obvious because there is nothing unobvious in the addition of known substances for known purposes. See particularly page 3, page 4, page 5, page 9 and page 11.

Claims 1, 2, 5-8, and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the provided translation of SE 463,493.

SE 463,493 discloses a dental cement composition comprising powdered calcium aluminate compounds of the phases claimed herein and methods for the production thereof. They are considered to be present in amounts greater than 50%. They can also contain sulfates, phosphates, silicates, apatites and carbonates of calcium or other metals as found in applicants dependent claims. They disclose cellulose materials as set forth in the dependent claims. They recite a powder particle size commensurate with that set forth herein. They disclose sintering, which would

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remove organic material. They disclose articles consistent with the claims herein. They disclose aqueous solutions to cure the material. They disclose superplasticizer component as set forth in the dependent claims. See particularly page 2, last 2 paragraphs, page 3, second half, page 4 and the examples.

SE 463,493 is considered to differ from the instant claims in that they don't recite the claimed requirements of less than 50 vol.% of CA_2 and less than 10 vol.% of C_3A . However, since these amounts include zero, the instant claims would have been obvious.

Since the composition of SE 463,493 is substantially the same as that disclosed by applicants, limitations such as expansion and temperature generation are considered inherent to the composition.

Claims 3, 4 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over SE 463,493 as applied to the claims above, and further in view of SE 010441-1.

These claims simply recite well-known additives in dental cement materials such as perovskites, LiCl, fumed silica, superplasticizers, water-reducing agents, etc. SE 010441-1 is relied upon only to demonstrate that these additives are known and would have been obvious because there is nothing unobvious in the addition of known substances for known purposes. See particularly page 3, page 4, page 5, page 9 and page 11.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SE 010441-1.

SE 010441-1 discloses a dental cement composition comprising powdered calcium aluminate compounds of the phases claimed herein and methods for the production thereof. They are considered to be present in amounts greater than 50%. They can also contain sulfates, phosphates, silicates, apatites and carbonates of calcium or other metals as found in applicants dependent claims. They disclose cellulose materials as set forth in the dependent claims. They recite a powder particle size commensurate with that set forth herein. They disclose sintering, which would remove organic material. They disclose articles consistent with the claims herein. They disclose aqueous solutions to cure the material. They disclose superplasticizer component as set forth in the dependent claims. The reference also recites the herein-claimed well-known additives in dental cement materials such as perovskites, LiCl, fumed silica, superplasticizers, water-reducing agents, etc. See particularly page 3, page 4, page 5, page 9 and page 11.

SE 010441-1 is considered to differ from the instant claims in that they don't recite the claimed requirements of less than 50 vol.% of CA_2 and less than 10 vol.% of C_3A . However, since these amounts include zero, the instant claims would have been obvious.

Since the composition of SE 010441-1 is substantially the same as that disclosed by applicants, limitations such as expansion and temperature generation are considered inherent to the composition.

The limitations of all claims are considered to be met by SE 010441-1.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/673,250. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ from one another only in the scope of coverage being sought. They appear to differ from one another only in the specification of the CA phases present in the composition. However, it would appear that the phases are no different from one another since the hydrated CA of the copending application fully encompasses that claimed herein by applicants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant is advised that any evidence to be provided under 37 CFR 1.131 or 1.132 and any amendments to the claims and specification should be submitted prior to final rejection to be considered timely. It is anticipated that the next office action will be a final rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth D. Wood whose telephone number is 571-272-1377. The examiner can normally be reached on M-F, 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, David Sample, can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ELIZABETH D. WOOD
PRIMARY EXAMINER
AU 1755